

**REMARKS**

This is a response to the Office Action mailed January 11, 2005. Claims 25-28, 32-53, and 58-74 are pending in the application. Claims 25-28, 32-53, and 58-74 have been rejected by the Examiner. The captions for claims 30-31 and 54-57 have been amended.

**Improper Captioning**

The Examiner noted the use of the term “deleted” in the captions for claims 30-31 and 54-57 is improper. The captions have been changed to “cancelled.”

**Claim Rejections - § 103**

The Examiner has rejected Claims 25-28, 32-53, and 58-74 under 35 U.S.C. § 103(a) as being unpatentable by Helmus (U.S. Patent Pub. No. 2002/0032477 A1) in view of Kay et al. (U.S. Patent No. 6,502,767). Applicant respectfully disagrees.

The Examiner states that Helmus teaches “stents (title) with spray coatings thereon (para0016).” The Examiner also states Helmus “fails to teach a cold spray process.” The Examiner claims that “it would have been obvious to one having ordinary skill in the art at the time of the invention to employ the cold spray process of Kay to coat the stents of Helmus in order to attain greater coating system flexibility.” The applicant respectfully disagrees.

“Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some **teaching, suggestion, or motivation** to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art.” MPEP 2143.01. According to

the Examiner, “the motivation to employ the cold spray process of Kay to coat the stents of Helmus is found at col. 2, lines 26-30 of Kay, where coating system flexibility is taught:”

It is another object of this invention to heat the gas and/or gases at a location remote from the spray gun which permits greater flexibility in system design for application onto substrates. (col. 2, lines 26-27 of Kay et al.)

The flexibility provided by heating gas and/or gases at a location remote from the spray gun is **analogous and relevant only to a cold spray system**. “The examiner must determine what is ‘**analogous prior art**’ for the purpose of analyzing the obviousness of the subject matter at issue. ‘In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be **reasonably pertinent to the particular problem with which the inventor was concerned**.’ *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).” MPEP 2141.01(a).

As indicated by the Examiner, Helmus fails to teach cold spraying. Helmus teaches that the “coating may be applied by dipping or **spraying using evaporative solvent materials** of relatively high vapor pressure to produce the desired viscosity and coating thickness.” (para. 0016 of Helmus) Thus, the spraying techniques applied in Helmus and Kay et al. are unrelated and not analogous.

Therefore, the flexibility provided by the cold spray method of Kay et al. is not a motivation to combine Helmus with Kay et al. since such flexibility is an advantage relevant only to cold spraying. More specifically, the ability to “heat the gas and/or gases at a location remote from the spray gun” is relevant to cold spraying and does not apply to the spraying method of Helmus.

**Claims 25 -28 and 32-42**

Claim 25 recites: “thermally spray-forming material onto the medical device to form a coating where the type of thermal spray processing is selected from the group consisting of cold spray, combustion, high velocity oxygen fuel, and plasma.” As indicated by the Examiner, Helmus does not teach or suggest the above-mentioned features recited in claim 25. In particular, Helmus does not teach or suggest cold spray thermal processing. Kay et al. cannot be used to cure the deficiencies of Helmus since the cold spray process to Kay et al. is not analogous to Helmus and there is no teaching, suggestion, or motivation to combine the cold spray process of Kay et al. to coat the stents of Helmus. Therefore, claim 25 is not obvious by Helmus in view of Kay et al. Thus claim 25 is patentably allowable. Applicant requests removal of the obviousness rejection of claim 25

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Applicant submits that claim 25 is nonobvious. Claims 26-28 and 32-42 depend from claim 25 and are allowable for at least the same reason that claim 25. Therefore, applicant requests removal of the obviousness rejections of claims 26-28 and 32-42.

#### **Claim 43**

Claim 43 recites the features of a method of coating “through cold spray thermal processing, comprising: introducing particles of a powder ... into a gas; introducing the gas and particles into a supersonic nozzle ...; directing the high pressure stream at a stent ...” Helmus does not teach cold spray thermal processing. For the reasons discussed above, Kay et al. cannot be used to cure the deficiencies of Helmus. Therefore, claim 43 is not obvious by Helmus in view of Kay et al. Thus, claim 43 is patentably allowable. Therefore, applicant requests removal of the obviousness rejection of claim 43.

**Claims 44-53 and 58-67**

Helmus does not teach the feature of cold spray thermal processing in claims 44, 58, 61, 64, 65, 66, and 67. For the reasons discussed above, Kay et al. cannot be used to cure the deficiencies of Helmus. Therefore, claims 44, 58, 61, 64, 65, 66, and 67 are not obvious by Helmus in view of Kay et al. Thus, claims 44, 58, 61, 64, 65, 66, and 67 are patentably allowable. Claims 45-53 depend from claim 44 and are allowable for at least the same reason that claim 44 is allowable. Claims 59-60 depend from claim 58 and are allowable for at least the same reason that claim 58 is allowable. Claims 62-63 depend from claim 61 and are allowable for at least the same reason that claim 61 is allowable. Therefore, applicant requests removal of the obviousness rejections of claims 44-53 and 58-67.

**Claims 68-72**

Helmus does not teach the feature of a thermal spray process in claims 68 and 71-72. For the reasons discussed above, Kay et al. cannot be used to cure the deficiencies of Helmus. Therefore, claims 68 and 71-72 are not obvious by Helmus in view of Kay et al. Thus, claims 68 and 71-72 are patentably allowable. Claims 69-70 depend from claim 68 and are allowable for at least the same reason that claim 68 is allowable. Therefore, applicant requests removal of the obviousness rejections of claims 68-72.

**Claims 73-74**

Claim 73 recites: "applying the coating material to the medical device using a thermal spray process, wherein the type of thermal spray process is selected from the group consisting of high velocity oxygen fuel and plasma." Helmus does not teach a "high velocity oxygen fuel" or a "plasma" thermal spray process. As indicated by the Examiner, Kay et al. teaches a cold spray process. In the telephone conversation with the Examiner on April 7, 2005, the Examiner

indicated that Kay et al. would not apply to a claim that does not include the “cold spray process” as a member of a Markush group: “thermal spray process is selected from the group consisting of ...” Thus, Kay et al. cannot be used to cure the deficiencies of Helmus. Thus, claim 72 is patentable allowable. Claim 73 depends from claim 72 and is allowable for at least the same reason that claim 72 is allowable. Therefore, applicant requests removal of the obviousness rejection of claims 73-74.

**Claim Rejections - Double Patenting**

**The 038 Publication in view of Kay et al.**

The Examiner has provisionally rejected Claims 25-28, 32-53, and 58-74 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/283,951 (as recited in US 2004/0088038 A1; “the 038 publication”) in view of Kay et al. Applicant respectfully disagrees.

The Examiner claims that “it would have been obvious to one having ordinary skill in the art at the time of the invention to employ the cold spray process and the metal alloy coatings of Kay to coat the stents of the 038 publication in order to give the manufacturer greater flexibility in processing.” The applicant respectfully disagrees.

As indicated by the Examiner, the 038 publication “fails to teach cold spray coating.” Claim 1 of the 038 publication recites “a stent” “wherein a thin layer of a polymeric material is applied to an outer surface of the tubular member.” The 038 publication teaches that “the thin layer of polymeric material is applied to the outer surface of the tubular member by known methods in the art, such as by coating and dipping. (para. 0028 of the 038 publication) As discussed above, the coating techniques in the 038 publication and Kay et al. are unrelated and not analogous. Therefore, the flexibility provided by the cold spray method of Kay et al. is not a

motivation to combine the 038 publication with Kay et al. since such flexibility is an advantage relevant only to cold spraying.

**Claims 25 -28 and 32-42**

Claim 25 recites: “thermally spray-forming material onto the medical device to form a coating where the type of thermal spray processing is selected from the group consisting of cold spray, combustion, high velocity oxygen fuel, and plasma.” As indicated by the Examiner, the 038 publication does not teach or suggest the above-mentioned features recited in claim 25. In particular, The 038 publication does not teach or suggest cold spray thermal processing. Kay et al. cannot be used to cure the deficiencies of the 038 publication since the cold spray process to Kay et al. is not analogous to the 038 publication and there is no teaching, suggestion, or motivation to combine the cold spray process of Kay et al. to coat the stents of the 038 publication. Therefore, claim 25 is not unpatentable over the 038 publication in view of Kay et al. Thus claim 25 is patentably allowable. Applicant requests removal of the rejection of claim 25.

Claims 26-28 and 32-42 depend from claim 25 and are allowable for at least the same reason that claim 25. Therefore, applicant requests removal of the rejections of claims 26-28 and 32-42.

**Claim 43**

Claim 43 recites the features of a method of coating “through cold spray thermal processing, comprising: introducing particles of a powder ... into a gas; introducing the gas and particles into a supersonic nozzle ...; directing the high pressure stream at a stent ...” The 038 publication does not teach cold spray thermal processing. For the reasons discussed above, Kay et al. cannot be used to cure the deficiencies of the 038 publication. Therefore, claim 43 is not

unpatentable over the 038 publication in view of Kay et al. Thus, claim 43 is patentably allowable. Therefore, applicant requests removal of the rejection of claim 43.

**Claims 44-53 and 58-67**

The 038 publication does not teach the feature of cold spray thermal processing in claims 44, 58, 61, 64, 65, 66, and 67. For the reasons discussed above, Kay et al. cannot be used to cure the deficiencies of the 038 publication. Therefore, claims 44, 58, 61, 64, 65, 66, and 67 are not unpatentable over the 038 publication in view of Kay et al. Thus, claims 44, 58, 61, 64, 65, 66, and 67 are patentably allowable. Claims 45-53 depend from claim 44 and are allowable for at least the same reason that claim 44 is allowable. Claims 59-60 depend from claim 58 and are allowable for at least the same reason that claim 58 is allowable. Claims 62-63 depend from claim 61 and are allowable for at least the same reason that claim 61 is allowable. Therefore, applicant requests removal of the rejections of claims 44-53 and 58-67.

**Claims 68-72**

The 038 publication does not teach the feature of a thermal spray process in claims 68 and 71-72. For the reasons discussed above, Kay et al. cannot be used to cure the deficiencies of the 038 publication. Therefore, claims 68 and 71-72 are not unpatentable over the 038 publication in view of Kay et al. Thus, claims 68 and 71-72 are patentably allowable. Claims 69-70 depend from claim 68 and are allowable for at least the same reason that claim 68 is allowable. Therefore, applicant requests removal of the rejections of claims 68-72.

**Claims 73-74**

Claim 73 recites: “applying the coating material to the medical device using a thermal spray process, wherein the type of thermal spray process is selected from the group consisting of high velocity oxygen fuel and plasma.” The 038 publication does not teach a “high velocity

oxygen fuel” or a “plasma” thermal spray process. As indicated by the Examiner, Kay et al. teaches a cold spray process. In the telephone conversation with the Examiner on April 7, 2005, the Examiner indicated that Kay et al. would not apply to a claim that does not include the “cold spray process” as a member of a Markush group: “thermal spray process is selected from the group consisting of ...” Thus, Kay et al. cannot be used to cure the deficiencies of the 038 publication. Thus, claim 72 is patentable allowable. Claim 73 depends from claim 72 and is allowable for at least the same reason that claim 72 is allowable. Therefore, applicant requests removal of the rejections of claims 73-74.

**Application No. 10/331,838**

The Examiner has provisionally rejected Claims 25-28, 32-53, and 58-74 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 12, 15-21, and 29-31 of copending Application No. 10/331,838.

At this point neither the Examiner nor Applicants know the scope or content of the claims that will be found allowable from this application or copending applications. Once that information is known, if the obviousness-type double patenting rejection is still appropriate, Applicants will promptly file a terminal disclaimer over Application No. 10/331,838. Please hold this double patenting rejection in abeyance until then.

**CONCLUSION**

Claims 25-28, 32-53, and 58-74 are pending in this application. Applicant respectfully submits that rejected Claims 25-28, 32-53, and 58-74 are in condition for allowance. Applicant respectfully requests the Examiner to pass the case to issue.

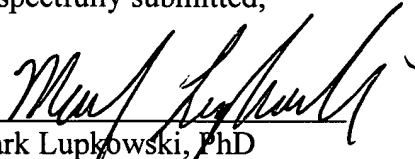


If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 954-0297.

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